

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN 04/01/96 OUT 04/26/96

Srinivas Gowda
Reviewed by Srinivas Gowda Date 04/26/96
EPA Reg. No. 65402-1
IAN Code _____
Date Division Received 03-11-96
Type Product Food Contact Surface Sanitizer
MRID No (s) 439492-01 to 439492-05
Product Manager PM 32 (Johnson)
Product Name VogorOx Liquid Sanitizer
Company Name FMC Corporation
Submission Purpose Amendment to add additional claims with
efficacy data and revised label
Type Formulation Liquid
Active Ingredient (s): _____ %
PeroxyaceticAcid.....5.1
HydrogenPeroxide.....21.7

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202.0 Recommendations

202.2 Efficacy Supported by the Data:

- a. "AOAC Use Dilution Test" by Daniela G. Bechara, MicroBio Test, Inc. (MBT), 14280 Sullyfield Circle, Suite 200, Chantilly, Virginia 22021, dated 04-28-94 (MRID No. 439492-01)

The submitted data by the AOAC Use Dilution Test Method are acceptable to support effectiveness of the product as a hospital disinfectant against Salmonella choleraesuis ATCC 10708, Staphylococcus aureus ATCC 6538, and Pseudomonas aeruginosa ATCC 15442 at a 1:199 dilution (5 ml of the disinfectant + 995 ml of 513 ppm CaCO₃ hard water) on pre-cleaned, hard, non-porous surfaces in the presence of 513 ppm CaCO₃ hard water for a contact time of 10 minutes at 20°C. However the following additional information is required to complete the submitted data report: Verify that the test substance employed in the AOAC Use Dilution Test (Flocide 375) is same as VigorOx Liquid Sanitizer and Disinfectant.

yes - see
1/16/96
SRS
correspondence

- b. "Inanimate non-food contact surface sanitizer test results. The evaluation of the efficacy of vigor Ox Liquid Sanitizer Against Klebsiella pneumonia" by Mary K. Bennett, M.T., ViroMed Laboratories, Inc., 6101 Blue Circle Drive, Minneapolis, MN 55343, dated 07-11-95 (MRID No. 439492-02)

The submitted efficacy data developed by the Non-Food Contact Surface Sanitizer Test Method are acceptable to support effectiveness of the product as a non-food contact surface sanitizer against Klebsiella pneumoniae ATCC 4352 when used at a 1:2048 dilution (1 ml of disinfectant + 2047 ml of tap water. 1 oz./16 gallons) on pre-cleaned, hard, non-porous surfaces for a contact time of 5 minutes at room temperature.

- c. "Inanimate non-food contact surface sanitizer test results. The evaluation of the efficacy of vigor Ox Liquid Sanitizer Against Staphylococcus aureus" by Mary K. Bennett, M.T., ViroMed Laboratories, Inc., 6101 Blue Circle Drive, Minneapolis, MN 55343, dated 08-29-95 (MRID No. 439492-03)

The submitted efficacy data developed by the Non-Food Contact Surface Sanitizer Test Method are acceptable to support effectiveness of the product as a non-food contact surface sanitizer against Staphylococcus aureus ATCC 6538 when used at a 1:2048 dilution (1 ml of disinfectant + 2047 ml of tap water. 1 oz./16 gallons) on pre-cleaned, hard, non-porous

surfaces for a contact time of 5 minutes at room temperature.

- d. "Inanimate non-food contact surface sanitizer test results. The evaluation of the efficacy of vigor Ox Liquid Sanitizer Against Staphylococcus aureus" by Mary K. Bennett, M.T., ViroMed Laboratories, Inc., 6101 Blue Circle Drive, Minneapolis, MN 55343, dated 09-28-95 (MRID No. 439492-04)

The submitted efficacy data developed by the Non-Food Contact Surface Sanitizer Test Method are acceptable to support effectiveness of the product as a non-food contact surface sanitizer against Staphylococcus aureus ATCC 6538 when used at a 1:2048 dilution (1 ml of disinfectant + 2047 ml of tap water. 1 oz./16 gallons) on pre-cleaned, hard, non-porous surfaces for a contact time of 5 minutes at room temperature.

- e. "Inanimate non-food contact surface sanitizer test results. The evaluation of the efficacy of vigor Ox Liquid Sanitizer Against Saccharomyces cerevisiae" by Mary K. Bennett, M.T., ViroMed Laboratories, Inc., 6101 Blue Circle Drive, Minneapolis, MN 55343, dated 07-11-95 (MRID No. 439492-04)

The submitted efficacy data developed by the Non-Food Contact Surface Sanitizer Test Method are acceptable to support effectiveness of the product as a non-food contact surface sanitizer against Saccharomyces cerevisiae ATCC 834 when used at a 1:2048 dilution (1 ml of disinfectant + 2047 ml of tap water. 1 oz./16 gallons) on pre-cleaned, hard, non-porous surfaces for a contact time of 5 minutes at room temperature.

203.0

Labeling:

- a. Under the heading "General Environmental Surfaces Sanitization (Non-food Contact)" change "...allow contact for at least 2 minutes" to read "...allow contact for at least 5 minutes."
- b. Under the heading "Spray Application" change "...allow to soak for at least 2 minutes (for sanitizing)..." to read "...allow to soak for at least 5 minutes (for sanitizing)..."
- c. Delete the entire paragraph under the heading "Use in Reformulation of Other Registered Products" because such statements are not allowed on the end use products labels.

- d. 1. Substitution of the word "sanitize" by the word "disinfectant" for ultrafiltration and Reverse Osmosis (RO) Membranes on the draft label is not acceptable. Remove the word "disinfect" and replace it with "sanitize" wherever it appears in conjunction with ultrafiltration and Reverse Osmosis (RO) Membranes.

2. Also add the following "SANITIZATION OF REVERSE OSMOSIS MEMBRANES" Note to the "Directions for Sanitization of Ultrafiltration and RO Membranes":

SANITIZATION OF REVERSE OSMOSIS MEMBRANES: "This product has been shown to be an effective disinfectant when tested by AOAC and EPA methods. This product may not totally eliminate all vegetative microorganisms in reverse osmosis membranes and their associated piping systems due to their construction and/or assembly, but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed."

- e. Include EPA and FDA's MOU statement. See attached PR Notice 94-4:

ATTACHMENT

JUNE 30, 1994

PESTICIDE REGULATION (PR) NOTICE 94-4

NOTICE TO MANUFACTURERS, FORMULATORS, PRODUCERS AND REGISTRANTS OF PESTICIDE PRODUCTS

As part of the EPA registration process, EPA will require registrants of liquid chemical germicides, other than sterilants that have received FDA premarketing clearance or approval, to put the following statement on their product labels:

"This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection."

NOTE TO PM: Please resubmit a label incorporating the above changes for EETMS review to complete the amendment process.